K090736

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MAY 20 2009

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:
Eileen M. Boyle
(978) 421-9171

Date Summary Prepared: March 10, 2009

Device: Power Infuser

Classification: Infusion Pump: Class II (21 CFR 880.5725)

Reason for submission: Change in the Intended Use

Description:

The Power Infuser model M100B-3A, reviewed and cleared under (K030739) is a miniature battery-operated infusion pump designed to deliver IV fluids and blood products to patients in the field, in pre-hospital transport, or in the hospital. When used with the Crystalloid/Colloid Cartridge, the device infuses crystalloid and colloid IV fluids, the most common initial therapy used to restore a patient's blood pressure and intravascular volume in both pre-hospital and hospital settings. When the device is used with the Blood Cartridge, it is intended to deliver crystalloid and colloid resuscitative fluids as well as whole blood and packed red blood cells. The device is not intended to support the delivery of any pharmaceutical or other medications.

The current indication for use is to restore volume and blood pressure to patients experiencing clinical shock, hypotension, and hypoperfusion states as a result of hemorrhagic blood loss, occult hemorrhage, neurogenic shock and septic shock. The indication is being expanded to administer fluids to any patient requiring continuous or intermittent delivery of IV fluids, whole blood, or packed red blood cells. The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments. The device is not intended to support the delivery of any pharmaceutical or other medications.

A previous 510(k) submissions demonstrated substancial equivalence to the David Clark Pressure Infuser for an I.V. bag (K820159 as required by 21 CFR Part 880.5420). The purpose of this submission is to more closely align the Intended Use of the Power Infuser to the predicate device as described below.

Intended Use:

The Power Infuser® Model M100B-3A is intended for continuous or intermittent administration of therapeutic and clinically appropriate intravenous fluids, blood and packed red blood cells through clinically acceptable access points.

The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments.

When used with the **Crystalloid/Colloid Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids. It is **not** intended to support the infusion of blood or blood products.

When used with the **Blood Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood.

The device is **not** intended to support the delivery of any pharmaceutical or other medications.

Substantial Equivalence:

The features and functions of the Power Infuser M100B-3A are substantially equivalent to the current features and functions of the Power Infuser.

Comparison of Technological Characteristics

The Power Infuser design characteristics have not been changed from the original design, which was reviewed and cleared by FDA as a result of this update.

Performance Testing:

Since the design and functionality of the Power Infuser M100B-3A has not changed, performance testing was not conducted. This submission is focused on the change to the Intended Use Statement.

Conclusion

Performance of the Power Infuser M100B-3A has not changed and remains substantially equivalent to those of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness. No software or hardware changes have been implemented into the device since the predicate (K030739) as a result of this update.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Ms. Eileen M. Boyle
Regulatory Affairs Specialist
Zoll Medical Corporation
269 Mill Road
Chelmsford, Massachusetts 01824

Re: K090736
Trade/Device Name: Power Infuser
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 10, 2009
Received: March 19, 2009

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K090736

Device Name: **Power Infuser**

Intended Use:

The Power Infuser® Model M100B-3A is intended for continuous or intermittent administration of therapeutic and clinically appropriate intravenous fluids, blood and packed red blood cells through clinically acceptable access points.

The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments.

When used with the **Crystalloid/Colloid Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids. It is **not** intended to support the infusion of blood or blood products.

When used with the **Blood Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood.

The device is **not** intended to support the delivery of any pharmaceutical or other medications.

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090736

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)